

EXHIBIT 1

PPE Specification No. 0012841 | Rev:4
Labeling Specification 28 Nov 2014
RMC P15506 GyneCare TTVT54254
Device Release Level: 4. Production
**GYNECARE™
TTVt™**

Tension-free Support
for Incontinence

GYNECARE TTVt™

Tension-free Vaginal Tape

GYNECARE TTVt™ Single Use Device

GYNECARE TTVt™ Reusable Introducer

GYNECARE TTVt™ Reusable Rigid Catheter Guide

GYNECARE TTVt™ anordning til engangsbrug

GYNECARE TTVt™ indfører til flergangsbrug

GYNECARE TTVt™ stift guiding kateter til flergangsbrug

GYNECARE TTVt™ hulpmiddel voor eenmalig gebruik

GYNECARE TTVt™ herbruikbare introducer

GYNECARE TTVt™ herbruikbare starre kathetervoerder

GYNECARE TTVt™ -laite, kestävä käytössä

GYNECARE TTVt™ -sisä/in viejä, kestokäytöinen

GYNECARE TTVt™ -kateteri, nohjaus, kestokäytöinen, jääkkäävä

Dispositif GYNECARE TTVt™ à usage unique

Introducator réutilisable GYNECARE TTVt™

Guide de sonde réicide réutilisable GYNECARE TTVt™

GYNECARE TTVt™ Einmalimplantat

GYNECARE TTVt™ wiederverwendbares Einführungsinstrument

GYNECARE TTVt™ wiederverwendbare starre Katheterführung

Συσκευή μιας χρήσης GYNECARE TTVt™

Επαναχρησιμοποιησιμός εισαγωγέας GYNECARE TTVt™

Επαναχρησιμοποιησιμός ακαμπτος οδηγός καθετήρα

GYNECARE TTVt™

Dispositivo monouso GYNECARE TTVt™

Introduttore riutilizzabile GYNECARE TTVt™

Guida rigida riutilizzabile per catetere GYNECARE TTVt™

Dispositivo de utilização única GYNECARE TTVt™

Introdutor reutilizável GYNECARE TTVt™

Guia rígido de catéter reutilizável GYNECARE TTVt™

Sistema para um solo uso GYNECARE TTVt™

Introdutor reutilizable GYNECARE TTVt™

Guía de catéter rígida reutilizable GYNECARE TTVt™

GYNECARE TTVt™ produkt för engångsbruk

GYNECARE TTVt™ återanvändbar införare

GYNECARE TTVt™ återanvändbar stel kateterguide



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13. During Retropubic retraction, place the Needle tip towards the pre-marked abdominal exit site.
14. When the needle tip has reached the desired position, pull the GYNECARE™ TTV introduced from the Needle. Before the implant is pulled out, take care to the 18 French Foley catheter and perform a cystoscopy (no degree CMS recommended).
15. Once bladder integrity is confirmed, pull the Needle upward to bring the implant out through the abdominal exit site. Clamp the implant just below the Needle. Cut the implant between the connection to the Needle and the clamp.
16. The procedure is now repeated on the patient's other side while repeating steps 9 – 15. NOTE: IN ORDER TO MINIMIZE THE RISK OF BLADDER INJURY, IT IS IMPORTANT THAT THE BLADDER BE DISPLACED TO THE CONTRALATERAL SIDE USING THE MANEUVERS OUTLINED IN STEP 10.
17. The ends of the implant are then pulled upward to bring the implant (sling) loosely, i.e., without tension, under the midurethra. Adjust the implant so that leakage is reduced, allowing only a few drops of urinary leakage to occur under stress. For this, use patient feedback, i.e. coughing with a full bladder (approximately 300 mL).
18. Grasp the implant Sheaths that surround the implant with clamps, taking care not to grasp the implant. Then individually remove the implant Sheaths by gently pulling up on the clamps, away from the abdomen, one at a time. To avoid putting tension on the implant, a blunt instrument (scissors or forceps) should be placed between the urethra and the implant during removal of the implant Sheaths.
19. **NOTE: Premature removal of the sheath may make subsequent adjustments difficult.**
20. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture the implant.
21. Close the skin incisions with suture or surgical skin adhesive.
22. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

CONTRAINdications

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE Mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TTV procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TTV procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TTV System before employing the GYNECARE TTV Device. It is important that the tape be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the GYNECARE TTV procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TTV procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimize risks.
- Retropubic bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from the hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The Rigid Catheter Guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley catheter.
- When removing the Rigid Catheter Guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.